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(54) Title: **LIQUID FORMULATIONS WITH HIGH CONCENTRATION OF HUMAN GROWTH HORMONE (hGH) COMPRISING 1,2-PROPYLENE GLYCOL**

(57) Abstract: The present invention relates to liquid formulations of human growth hormone (hGH, somatropin) which are storage stable, show reduced or no crystallization on storage and are suitable for administration to the human or animal body. More particularly, the invention relates to liquid formulations of human growth hormone which are stable and exhibit minimal or no crystallization when stored at least for a time at temperature above refrigeration temperatures.

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INTERNATIONAL SEARCH REPORT

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A. CLASSIFICATION OF SUBJECT MATTER
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B. FIELDS SEARCHED

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Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ, BIOSIS, EMBASE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	EP 0 955 062 A (GENENTECH INC) 10 November 1999 (1999-11-10) page 5, line 5 -page 5, line 40; claims 15-21	1-29
P, Y	GB 2 371 227 A (GRANDIS BIOTECH GMBH) 24 July 2002 (2002-07-24) example II	1-29
A	US 5 567 677 A (HOEKBY ELVY ET AL) 22 October 1996 (1996-10-22) tables 1-3	1-29

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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INTERNATIONAL SEARCH REPORT

Information on patent family members

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Patent document cited in search report		Publication date	Patent family member(s)	Publication date
EP 0955062	A	10-11-1999	EP 0955062 A1	10-11-1999
			AT 197405 T	11-11-2000
			AU 686567 B2	12-02-1998
			AU 4792793 A	03-03-1994
			CA 2139358 A1	17-02-1994
			CA 2337745 A1	17-02-1994
			DE 69329651 D1	14-12-2000
			DE 69329651 T2	23-05-2001
			DK 652766 T3	29-01-2001
			EP 0652766 A1	17-05-1995
			ES 2153385 T3	01-03-2001
			GR 3035144 T3	30-04-2001
			IL 106524 A	31-08-2000
			JP 7509719 T	26-10-1995
			MD 960246 A	31-01-1998
			MX 9304613 A1	31-03-1994
			NZ 255158 A	22-09-1997
			PT 652766 T	30-04-2001
			WO 9403198 A1	17-02-1994
			US 5763394 A	09-06-1998
			US 2003013653 A1	16-01-2003
			US 2001007858 A1	12-07-2001
<hr/>				
GB 2371227	A	24-07-2002	WO 02067989 A1	06-09-2002
<hr/>				
US 5567677	A	22-10-1996	AT 196092 T	15-09-2000
			AU 3913593 A	08-11-1993
			CA 2102693 A1	04-10-1993
			DE 69329367 D1	12-10-2000
			DE 69329367 T2	21-06-2001
			DK 587858 T3	18-12-2000
			EP 0587858 A1	23-03-1994
			ES 2150940 T3	16-12-2000
			GR 3034925 T3	28-02-2001
			JP 3268557 B2	25-03-2002
			JP 6508156 T	14-09-1994
			NO 934355 A	01-12-1993
			NZ 251498 A	26-07-1995
			PT 587858 T	28-02-2001
			WO 9319776 A1	14-10-1993
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